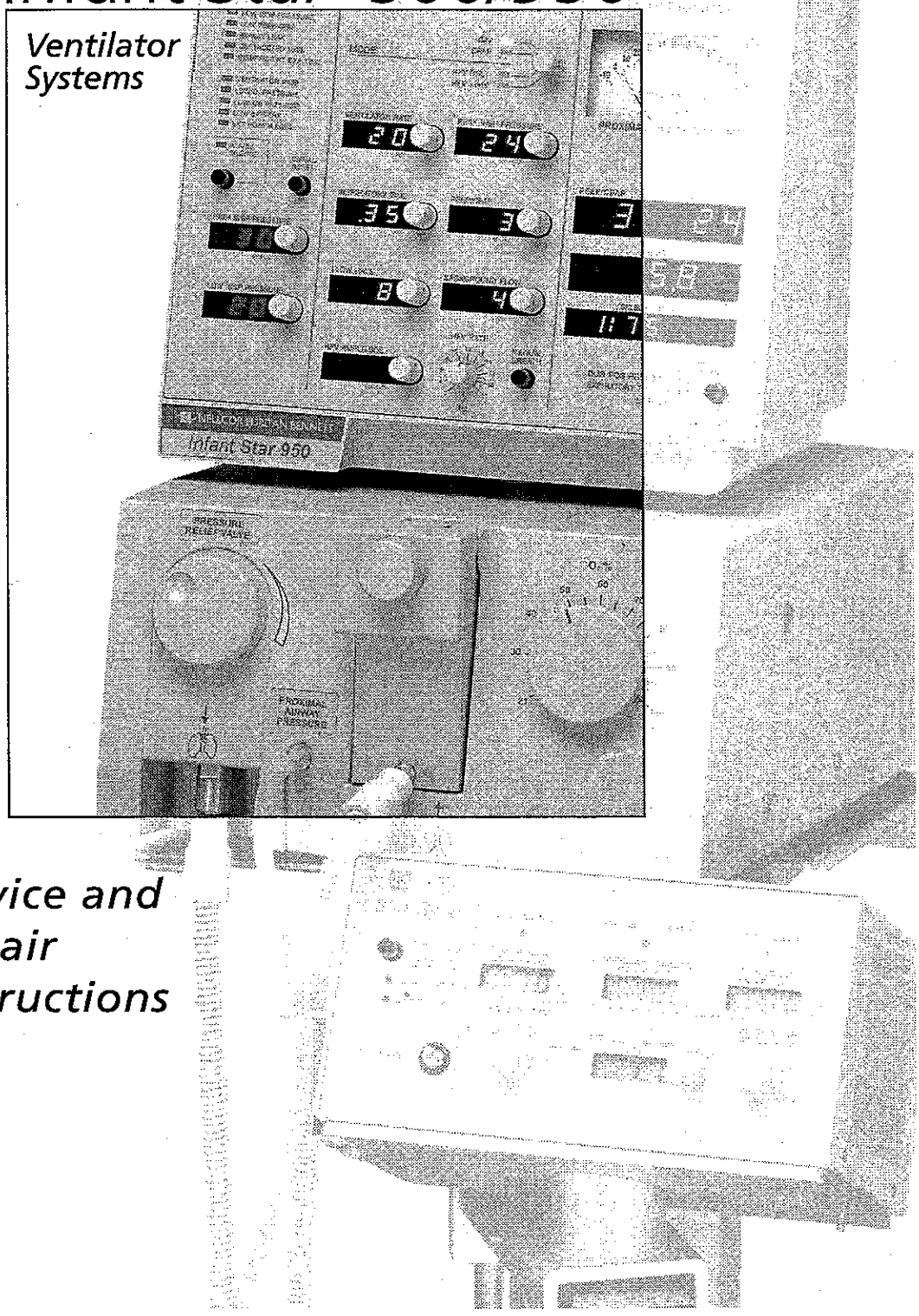
MALLINCKRODT

PURITAN-BENNETT

# Infant *Star*® 500/950

*Ventilator Systems*




## *Service and Repair Instructions*

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## Authorized Service

This manual is intended for use by Mallinckrodt trained and authorized Service Personnel. Any adjustments or procedures that exceed the scope of this manual should be referred to Mallinckrodt.

Mallinckrodt does not condone or approve of service activity on its products by anyone other than Mallinckrodt trained and authorized personnel. Mallinckrodt is not responsible for any repairs made by unauthorized procedures or personnel.

Use of the incorrect part or failure to exercise due care in the installation, removal, servicing, or calibration of parts and equipment may result in damage to the equipment and possible malfunction of the equipment, which may in turn result in damage to property and injury (including death) to persons. The purchaser and installer of these parts shall bear full responsibility and liability for the above.

For specific operating instructions and clinical theory of operation, refer to the Infant *Star* 500/950 Ventilator's Operating Instructions Manual. Service personnel should become familiar with the Operating and Repair techniques before servicing this equipment.

## Electromagnetic Susceptibility

The Infant *Star* 500/950 Ventilator Systems comply with the requirements of IEC 601-1-2 (EMC Collateral Standard), including the E-field susceptibility requirements at a level of 10 volts per meter, at frequencies from 26 MHz to 1 GHz, and the ESD requirements of this standard up to 6 kV direct and 15 kV air discharge. However, even at this level of device immunity, certain transmitting devices (cellular phones, walkie-talkies, cordless phones, paging transmitters, etc.) emit radio frequencies that could interrupt ventilator operation if their proximity is located too close to the ventilator. It is difficult to determine when the field strength of these devices becomes excessive. Practitioners should be aware that radio frequency emissions are additive, and that the ventilator must be located a sufficient distance from transmitting devices to avoid interruption. Do not operate the ventilator in a magnetic resonance imaging (MRI) environment. Section 9 describes possible ventilator alarms and what to do if they occur. Consult with your institution's biomedical engineering department in case of interrupted ventilator operation, and before relocating any life-support equipment.

## Definitions

This manual uses three special indicators to convey information of a specific nature. The text under each heading states the reason the heading is used. They are listed below:

**Warning**

Means there is a possibility for causing a potential safety hazard, which can result in an adverse reaction, or injury to the patient, you, or others.

**Caution**

Means that special care is to be exercised to protect against the possibility of damage to the instrument or other property.

**NOTE:**

Indicates points of particular interest for more efficient and convenient operation.

## Warnings, Cautions, and Notes

Please take the time to familiarize yourself with the following caveats as they cover safety considerations, special handling requirements, and regulations that govern the use of the Infant *Star* 500/950 ventilator systems.

- To ensure proper servicing and avoid the possibility of physical injury, only qualified personnel should attempt to service or make authorized modifications to the ventilator.

  The user of this product shall have sole responsibility for any ventilator malfunction due to operation or maintenance performed by anyone not trained by Mallinckrodt staff.

- To avoid an electrical shock hazard while servicing the ventilator, be sure to remove all power to the ventilator by disconnecting the power source and turning off all ventilator power switches.

  An electrical shock hazard is present inside the ventilator cabinet when the Vac power is connected, even though the power switch is in the OFF position. Always take appropriate safety precautions to avoid accidental shock.

  The ventilator has a "hospital grade" Vac Power cord and plug. Grounding reliability can only be assured when connected to a tested receptacle identified as "hospital grade." Tampering with or reconfiguring the cord or plug supplied with the unit may void the factory warranty, cause damage to the unit, or be injurious to those associated with its use.

- To avoid a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (for example, flammable anesthetics and/or heaters) away from the Infant *Star* 500/950 ventilator systems and oxygen hoses.

  Do not use oxygen hoses that are worn, frayed, or contaminated by combustible materials such as grease or oils. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

  In case of fire or a burning smell, immediately disconnect the ventilator from the oxygen supply, facility power, and backup power source.

- When handling any part of the Infant *Star* 500 or Infant *Star* 950 ventilator system, always follow your hospital infection control guidelines for handling infectious material.

  Mallinckrodt recommends that users of its products that require cleaning and sterilization/disinfection, consider the *National Standards and Recommended Practices for Sterilization* published by the Association for the Advancement of Medical Instrumentation (AAMI), as well as the following Center for Disease Control (CDC) publications: *Guidelines for Maintenance of In-use Respiratory Therapy Equipment and Guidelines for Prevention of Nosocomial Pneumonia.*

- Patients on life-support equipment should be appropriately monitored by competent medical personnel and suitable monitoring devices.

  The Infant *Star* 500/950 ventilator systems are not intended to be comprehensive monitoring devices and do not activate alarms for all types of dangerous conditions for patients on life-support equipment

- For a thorough understanding of ventilator operations, be sure to thoroughly read this manual before attempting ventilator service.

- Before activating the ventilator, be sure to check the equipment for proper operation and, if appropriate, run a Quick Checkout as described in Section 3 of this manual.

- Federal law (U.S.) restricts the sale of this device to, or by the order of, a physician.

- Check the ventilator periodically as outlined in this manual; do not use if defective. Immediately replace parts that are broken, missing, obviously worn, distorted, or contaminated.

- An alternate source of ventilation should always be available when using the Infant *Star* 500/950 ventilator systems.
- The Infant *Star* 500/950 ventilator systems are a member of the Infant *Star* family of products.

## Intended Use

The Infant *Star* is designed to provide continuous ventilatory support for neonatal and pediatric patients less than 40 lbs. (18 kg), with an adjustable FLOW RATE range of 4 to 40 liters per minute (LPM), and BACKGROUND FLOW range of 2 to 30 LPM (2 to 32 LPM software versions 107 and above).

## Functional Considerations

Verify that the ventilator is Y2K compliant. If the ventilator is noncompliant, it may display incorrect dates.

## Shipping instructions

A shipping container for the ventilator is available. To ensure proper preparation and shipping, contact Mallinckrodt for instructions.

## Applicability

This service manual is applicable to Infant *Star* 500/950 ventilators only.

Mallinckrodt reserves the right to change specifications and procedures without notice.

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SECTION 1

# Repair Statement/Program Implementation

## 1.1 Infant *Star* 500/950 Ventilators

**Caution**

Always adhere to electrostatic discharge control (ESD) procedures when servicing a ventilator.

Infant *Star*® 500/950 ventilators are designed, and technical support is provided, to allow service and repair by qualified personnel. This means personnel who routinely repair sophisticated electronic, mechanical, and pneumatic equipment; have been specifically trained to repair Mallinckrodt products.

If a medical facility and/or distributor does not provide service and repair, Mallinckrodt offers a complete service training program on Infant *Star* ventilators. For more information contact:

Mallinckrodt Inc.
1-800-635-5267
press 2 for Technical Support.

To support all levels of service and repair the following projects are on going:

- Comprehensive service manuals specialized tooling and testing instrumentation.
- Most Infant *Star* major subassemblies are available on an exchange basis.
- Mallinckrodt offers service and repair training classes to medical facility and distributor personnel. For more information contact Mallinckrodt Technical Support at the number listed above.

## 1.2 Preventive Maintenance

To reduce mechanical failures, it is important that a routine preventive maintenance program be followed to maintain a functional ventilator.

- Perform the Quick Checkout Procedure (described in Section 3) each time the ventilator is used for a new patient or, at a minimum, once a month.
- Perform the Extended Preventive Maintenance Test (described in Section 5) twice a year.

Regular service extends the life of the ventilator. Overhaul service is recommended after 10,000 hours or 7 years; whichever comes first.

Replace the pneumatic chassis at the 10,000 hour overhaul. During the 10,000-hour overhaul, other components are replaced based on age and usage, and install-free update. Electrical components are replaced or rebuilt to current specifications. For more information on overhaul programs, contact Mallinckrodt Technical Support at the number listed above.

SECTION 2

# Specifications

## 2.1 Infant *Star* 500/950 Ventilator Features

The Infant *Star* 500/950 ventilators are microprocessor controlled. The Infant *Star* 500 is a conventional neonatal ventilator whereas the Infant *Star* 950 offers both conventional neonatal and high-frequency ventilation (HFV) modes. The Infant *Star* 950 ventilator has an expanded pneumatic system and added control functions. These additional features provide conventional ventilation, high-frequency oscillatory type of ventilation, or a mixing of both.

The design and construction of the Infant *Star* 500/950 ventilators are identical, with the exception of the following features (see Table 2-1):

- The Infant *Star* 950 control panel MODE selector switch has two additional selections:
  - HFV ONLY (high-frequency ventilation)
  - HFV + IMV (high-frequency ventilation plus intermittent mandatory ventilation breaths)
- The Infant *Star* 950 control panel has two additional ventilator control potentiometers and an LED display:
  - HFV RATE (operator control for setting HFV breathing rate)
  - HFV AMPLITUDE (operator control for setting flow amplitude in HFV mode)

  The Infant *Star* 500 Control Panel does not have the additional components and graphic overlay covers that support HFV.
- The Infant *Star* 950 pneumatic system has four additional solenoid valves on the flow manifold in the manifold block: SV11 valves A and B, SV12 valves A and B. The solenoid low-voltage wiring is connected to the existing terminal block.
- To prevent unauthorized clinical use of the HFV mode, the Infant *Star* 950 has a keyed ON/OFF switch on the rear of the pneumatics compartment.
- The jet orifice, located in the exhalation block, is larger on the Infant *Star* 950 ventilator (non-CE mark) to accommodate HFV, as compared to the *Star* 500 ventilator (non-CE mark) which does not have HFV. Conversely, Infant *Star* 500/950 ventilators that are CE marked have the same size jet orifice. (CE mark ventilators have a needle valve on the venturi solenoid that adjust for HFV.)

**Table 2-1: Infant *Star* 500/950 Comparison Chart**

| Feature | Infant *Star* 950 | Infant *Star* 500 | Comments |
|---|---|---|---|
| HFV Mode ON/OFF key switch | Available -- Harness connection to Front Panel PCB | Not available | Switch and harness deleted, chassis hole plugged on Infant *Star* 500 |
| Mode Selector: HFV Only HFV + IMV | Available | Not available | |
| Controls: HFV Rate HFV Amplitude | Available | Not available | Potentiometers are deleted from existing front panel display PCB on Infant *Star* 500 |
| LED Display: HFV Amplitude | Available | Not available | LED deleted from existing front panel display PCB on Infant *Star* 500 |
| Solenoids: SOL11/SOL12 (2 ea.) | Installed on flow manifold | Not available | Valve ports plugged on flow manifold of Infant *Star* 500 |
| Exhalation Block Venturi Jet Orifice | CE mark and Non-CE mark ventilators: 0.032-in. ID orifice jet (blue) | Non-CE mark ventilators: 0.020-in. ID orifice jet (silver) CE-mark ventilator: 0.032-in. ID orifice jet (blue) | Infant *Star* 500 has *standard* Venturi Jet |

## 2.2 System Specifications

Table 2-2 below lists the Infant Star 500/950 ventilator system specifications.

**Table 2-2: System Specifications***

| Control/Parameter | Range |
|---|---|
| **FRONT CONTROL PANEL** **Alarms** High Insp. Pressure | 5 to 105 $cmH_2O$ (Infant *Star* 950 only) |
| Low Insp. Pressure | 3 to 60 $cmH_2O$ |
| Low PEEP/CPAP | |
| PEEP/CPAP Setting ($cmH_2O$) | Pressure difference for 25 seconds or longer between setting and proximal required to activate alarm ($cmH_2O$) |
| 0 to 5 | 2 |
| 6 to 8 | 3 |
| 9 to 12 | 4 |
| 13 to 24 | 5 |

**Table 2-2: System Specifications* (continued)**

| Control/Parameter | Range |
|---|---|
| **Alarms (continued)** | |
| Airway Leak | Leak makeup flow exceeds Background Flow by 13 Lpm for 4 seconds |
| Obstructed Tube | Detects any problems that cause:<br>• Proximal Pressure to rise to the HIP<br>• Prolonged or impeded exhalation<br>• PEEP/CPAP pressure to rise above the set point by 6 $cmH_2O$ for 5 seconds<br>• Internal pressure to rise above set HIP by 10 $cmH_2O$<br>• Internal pressure to rise above set HIP by 5 $cmH_2O$ |
| Insufficient Exp. Time | 0.3 seconds at rates 100 bpm<br>0.2 seconds at rates 100 bpm |
| Ventilator Inop | System malfunction or fully depleted internal battery |
| Low Oxygen Pressure | < 45 psig (310 kPa) (35 psi for Infant *Star* 500 with CE mark) |
| Low Air Pressure | < 45 psig (310 kPa) (35 psi for Infant *Star* 500 with CE mark) |
| Low Battery | Activates within 5 minutes prior to full-battery discharge |
| Ext Power Loss | Loss of ac power (battery life 30 minutes minimum - if fully charged) |
| Alarm Silence | 60 seconds |
| Visual Reset | Push to clear alarm indicators (except Power Loss and Ventilator Inop) |
| **VENTILATOR SETTINGS** | |
| Modes | • IMV<br>• CPAP<br>• HFV ONLY (Infant *Star* 950 only)<br>• HFV+IMV (Infant *Star* 950 only) |
| Ventilator Rate | 1 to 150 bpm |
| Peak Insp. Pressure | 5 to 90 $cmH_2O$ |
| Inspiratory Time | 0.1 to 3 seconds |
| PEEP/CPAP | 0 to 24 $cmH_2O$ |
| Flow Rate | 4 to 40 Lpm |
| Background Flow | 2 to 30 Lpm<br>2 to 32 Lpm (software version 107 and above) |
| High Insp. Pressure Alarm | 5 to 105 $cmH_2O$ |
| Low Insp. Pressure Alarm | 3 to 60 $cmH_2O$ |
| Manual Breath | Delivers single mandatory breath |
| HFV Rate (950 only) | 2 to 22 Hz |
| HFV Amplitude (950 only) | Varies pulse flow from 12 to 120 Lpm |

**Table 2-2: System Specifications* (continued)**

| Control/Parameter | Range |
|---|---|
| **PATIENT MONITOR** | |
| Proximal Airway Pressure | -10 to +120 $cmH_2O$ |
| Proximal PEEP/CPAP | -9 to +99 $cmH_2O$ |
| Peak Insp. Pressure (PIP) | 0 to 110 $cmH_2O$ |
| Proximal Mean | -9.9 to +99.9 $cmH_2O$ |
| Selected Data | Push button control allows a single display to be used for multiple measurements |
| Dur Pos Press | 0.02 to 5.0 seconds |
| Expiration Time | 0.2 to 59.9 seconds |
| I:E Ratio | 1:0.1 to 1:99.9 |
| **LOWER SECTION** | |
| Pressure Relief Valve | 5 to 120 $cmH_2O$ |
| Exhalation Block | Houses exhalation valve diaphragm and jet venturi |
| Oxygen % | 21 to 100 |
| **REAR PANEL CONTROL** | |
| Alarm | 72 to 88 decibels |
| Hours (Elapsed Hours Meter) | 0.0 to 99999.9 hours |
| To *Star Sync* | 9-pin DIN connector |
| ac Circuit Breaker (100/115 V) | 100 V – 2.0 amps<br>115 V – 1.2 amps |
| Mains/Battery Charger (220 V) | 220 V – 0.6 amps |
| dc Circuit Breaker | 12 V – 8.0 amps |
| 12 Vdc input | 11.8 to 18 V – 5 amp battery power source |
| ON/OFF Switch | Turns ventilator ON and OFF |
| RS-232 Serial Output Connection | 1200 baud |
| Analog Pressure Output | 10 mV / $cmH_2O$ – 0.1 to 1.2 V |
| Remote Alarm | 30 V - 0.25 amps |
| **INPUTS** | |
| Electrical – Nominal | |
| 100 V<br>115 V<br>220 - 240 V | 90 - 105 Vac, 50/60 Hz, 100 W<br>105 - 123 Vac, 50/60 Hz, 100 W<br>198 - 264 Vac, 50/60 Hz, 100 W |
| Pneumatics | Air and oxygen, 45 to 90 psig (309 to 619 kPa) |

**Table 2-2: System Specifications* (continued)**

| Control/Parameter | Range |
|---|---|
| **PHYSICAL CHARACTERISTICS** | |
| Ventilator | 16.25" high x 11.25" wide x 19.25" deep<br>(41 cm x 29 cm x 49 cm) |
| Weight | 50 lbs (23 kg) – does not include pedestal stand |
| Pedestal Stand | 44" high x 25" wide<br>(112 cm x 46 cm) |
| Weight | 14 lbs (6.4 kg) |
| * Specifications subject to change without notice. | |

SECTION 3

# Quick Checkout

## 3.1 Quick Checkout

### 3.1.1 Infant *Star* 500 Quick Checkout Procedure

NOTE:
Reference Figure 3-1 when performing this procedure.

1. Connect both source gases and electrical power; attach the breathing circuit, humidifier and test lung.
2. Turn circuit breaker (MAINS/Battery Charger) to the ON (I) position.
3. Turn ventilator ON/OFF switch to ON and note the software revision number in the SELECTED DATA display.

NOTE:
If during start up, any number under 103 appears in the SELECTED DATA display, the software level should be updated. Contact your local distributor or Mallinckrodt at 1-800-635-5267, press 2 for Technical Support.

4. All LED indicators are illuminated except Low Battery, Ventilator Inop., and Ext Power Loss. (The Ventilator Inop. may blink during power-up.)
5. The audible alarm is momentarily activated, verifying its function.
6. Set standard test conditions:

| | |
|---|---|
| **Mode** | IMV |
| **Ventilator Rate** | 30 bpm |
| **Peak Inspiratory Pressure** | 40 $cmH_2O$ |
| **Inspiratory Time** | 1.0 seconds |
| **PEEP/CPAP** | 0 $cmH_2O$ |
| **Flow Rate** | 20 Lpm |
| **Background Flow** | 4 Lpm |
| **High Inspiratory Pressure** | 45 $cmH_2O$ |
| **Low Inspiratory Pressure** | 30 $cmH_2O$ |
| **Selected Data** | Expiratory Time (seconds) |
| **Oxygen Percent** | 60 |
| **Pressure Relief Valve** | Fully clockwise |

NOTE:
After 30 seconds the MEAN display, located in the Patient Monitor portion of the control panel, is 19±2 $cmH_2O$ and the PIP display is 40 ±1 $cmH_2O$.

7. During a mechanical breath, kink the From Patient tube to prevent gas flow. Verify that the proximal pressure drops abruptly when the A03 OBSTRUCTED TUBE alarm activates.
8. Disconnect the To Patient tube at the ventilator and block the connector located under the pressure-relief valve. Verify that the HI PIP, A05 OBSTRUCTED TUBE, HIGH INSP. PRESSURE and LOW INSP. PRESSURE alarms activate and the displays illuminate. Reconnect the tube, cancel the audible alarm, then push VISUAL RESET button. Verify PEEP/CPAP display is 0 ±2 $cmH_2O$.
9. Enter the following settings:

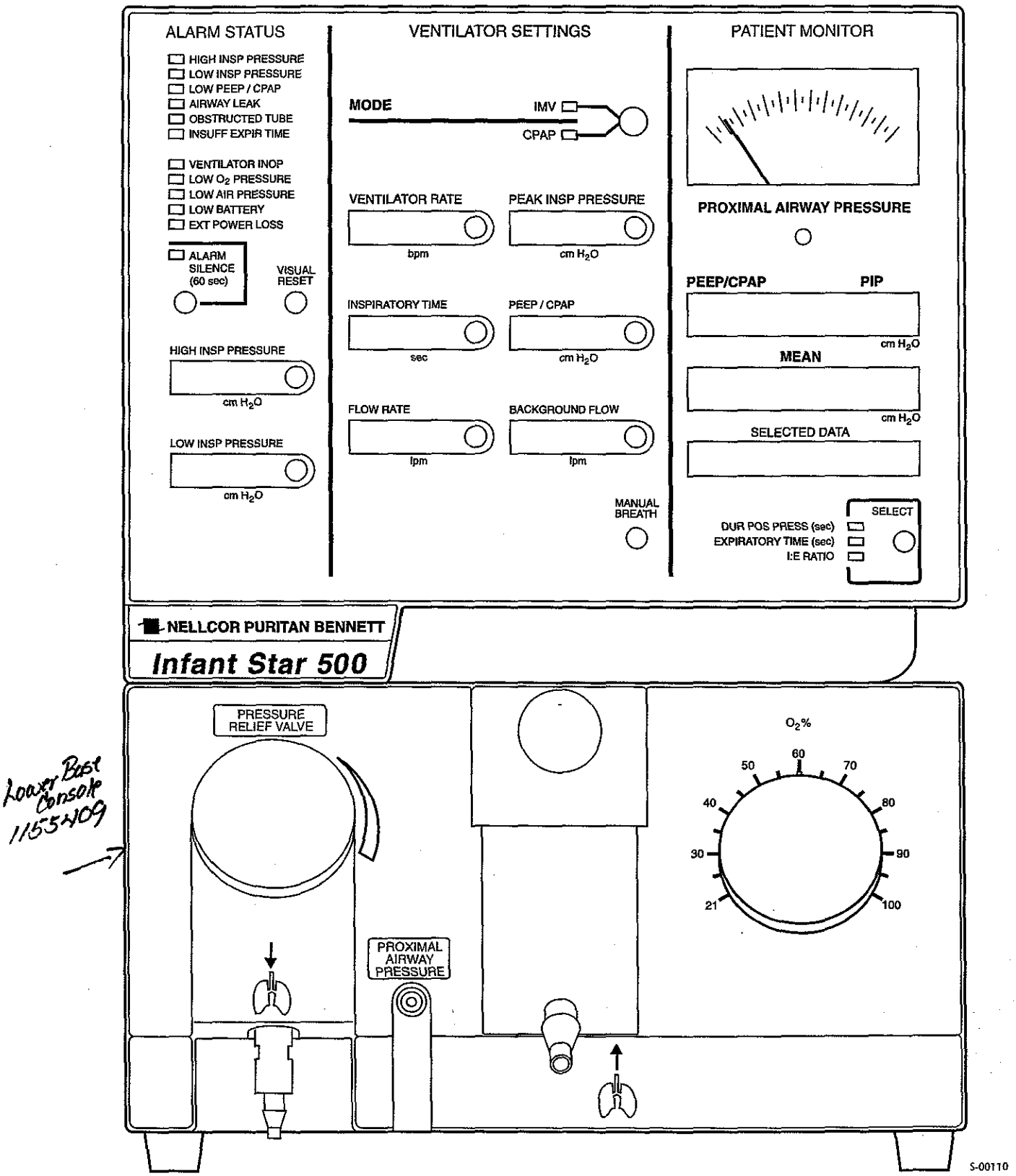
| | |
|---|---|
| **Mode** | CPAP |
| **PEEP/CPAP** | 10 $cmH_2O$ |
| **Flow Rate** | 8 Lpm |
| **Background Flow** | 8 Lpm |

NOTE:
After 30 seconds the Proximal Airway Pressure meter, PEEP/CPAP, MEAN, and PEEP/CPAP setting displays should read 10 ±1.

10. After checking at 10 $cmH_2O$, reset PEEP/CPAP to 20 $cmH_2O$ and again verify displays. After 30 seconds, the displays (mentioned in the note above) should read 20 ±2 $cmH_2O$.
11. If the unit passes the Quick Checkout procedure, it is ready for patient use. Set the ventilator according to the physician's orders before connecting it to a patient.
12. To verify functionality of the audible/visual alarms for low oxygen and low-air pressure, momentarily close off gas sources. The alarms should activate when gas pressures are removed and reactivate when gas pressures are reapplied.

**Warning**

If a mechanical or electrical problem is discovered while running the Quick Checkout procedure or while operating the ventilator, the ventilator must be removed from use and serviced by a certified biomedical technician or person with equivalent experience and training in this type of equipment.




Lower Base Console 1155409

**Figure 3-1. Infant *Star* 500 Ventilator**

### 3.1.2 Infant *Star* 950 Quick Checkout Procedure

**Warning**

If a mechanical or electrical problem is discovered while running the Quick Checkout procedure or while operating the ventilator, the ventilator must be removed from use and serviced by a certified biomedical technician or person with equivalent experience and training in this type of equipment.

**NOTE:**

The quick checkout procedure is based on using the following Mallinckrodt products:

- high-frequency breathing circuit (P/N – N-501023)
- standard test lung (P/N – N-1101262)

**NOTE:**

Reference Figure 3-2 when performing this procedure.

1. Connect the two source gases and electrical power, attach the patient circuit, humidifier, and test lung. Turn the ventilator power switch to the ON position.

   Verify:

   - All segments on all digital displays are illuminated and bright.
   - All LED indicators are illuminated except EXT POWER LOSS, VENTILATOR INOP, and LOW BATTERY. VENTILATOR INOP may blink during power-up.
   - An audible alarm momentarily sounds.
   - A software revision number appears in the SELECTED DATA window.

2. Set the following standard test conditions:

| | |
|---|---|
| **Mode** | IMV |
| **Ventilator Rate** | 30 bpm |
| **Peak Inspiratory Pressure** | 40 $cmH_2O$ |
| **Inspiratory Time** | 0,5 seconds |
| **PEEP/CPAP** | 0 $cmH_2O$ |
| **Flow Rate** | 20 Lpm |
| **Background Flow** | 4 Lpm |
| **High Inspiratory Pressure** | 45 $cmH_2O$ |
| **Low Inspiratory Pressure** | 3 $cmH_2O$ |
| **HFV Rate** | 12 Hz |
| **HFV Amplitude** | Fully counterclockwise |
| **Selected Data** | Expiratory Time (seconds) |
| **Oxygen Percent** | 60 |
| **Pressure Relief Valve** | Fully clockwise |
| **HFV Key** | ON |

Verify:

- No HFV oscillations can be heard
- PEEP/CPAP is 0 $cmH_2O$
- Peak Inspiratory Pressure is 40 ±1 $cmH_2O$
- MEAN Airway Pressure is 9 ±1 $cmH_2O$
- Expiratory Time is 1.5 seconds

1. During a mechanical breath, kink the From Patient tube to restrict gas flow. Verify that the proximal pressure drops abruptly when the AO3 OBSTRUCTED TUBE alarm activates.
2. Disconnect the To Patient tube at the ventilator connection and block the outlet. Verify the A05 OBSTRUCTED TUBE and LOW INSP. PRESSURE alarms and displays. Reconnect the tube; the alarm should stop. Push the VISUAL RESET button to clear the visual alarms.
3. Turn the Mode switch to HFV + IMV. Rotate the HFV Amplitude control fully clockwise. High-frequency pulses should be visible on the analog gauge and audible between each mechanical IMV breath. High-frequency pulses should not occur during an IMV breath. HFV Amplitude display should register at least 34 $cmH_2O$. HFV Amplitude levels will vary based on compressible volumes in the humidifier, breathing circuit, and test lung. For example, if the water level in the humidifier is low, the compressible volume increases and the amplitude decreases.
4. Rotate the HFV Rate control knob to 20 Hz. HFV pulses should be rapid (too fast to count). Turn the HFV Rate control knob back to 2 Hz; HFV should be relatively slow (approximately 3 pulses between each IMV breath). Set the HFV Rate back to 12 Hz.
5. Turn the HFV Amplitude control knob fully counterclockwise. The amplitude should incrementally decrease to a minimum of 6 to 13 $cmH_2O$.
6. Set the following:

| | |
|---|---|
| Mode | CPAP |
| PEEP/CPAP | 10 $cmH_2O$ |
| Background | 8 Lpm |
| HFV Key | OFF |

Verify: Low Ins Press Fully Counter Clockwise

- 10 $cmH_2O$ of PEEP appears in a total of five displays:
  - Proximal Airway Pressure gauge
  - PEEP/CPAP display in the Ventilator Settings portion of the control panel
  - MEAN Airway Pressure monitor display
  - PEEP/CPAP display in the Patient Monitor portion of the control panel
  - Low Inspiratory Pressure setting display
- There should be no high-frequency oscillations.

7. After checking at 10 $cmH_2O$, set the PEEP/CPAP control to 20 $cmH_2O$; again verify that the five displays (listed above) read 20 $cmH_2O$.

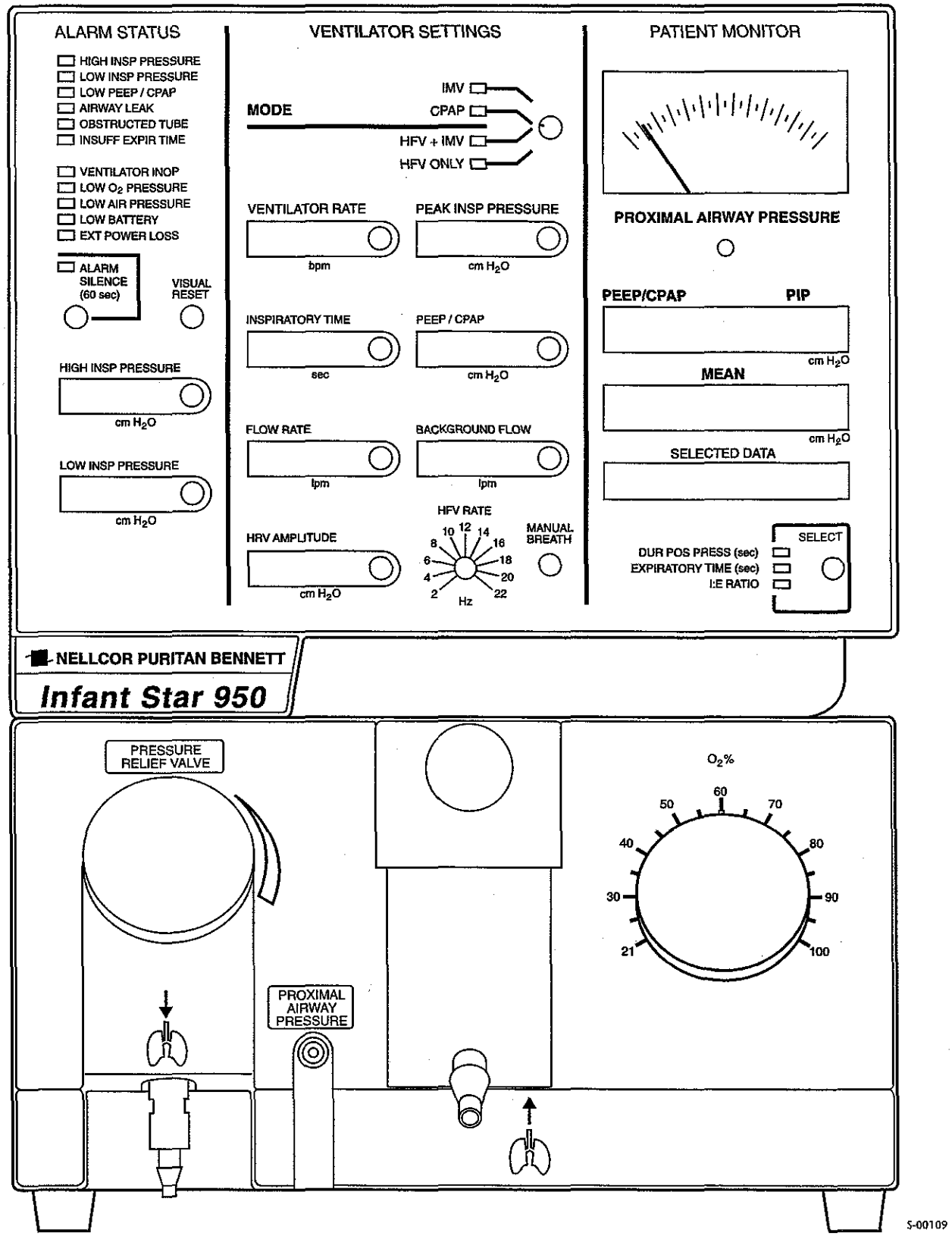



**Figure 3-2. Infant *Star* 950 Ventilator**

SECTION 4

# Theory of Operation

## 4.1 Introduction

**NOTE:**
The following information provides an overview of the Infant *Star* 500/950 ventilators. For an operational description, reference Section 7 for pneumatic and electronic schematics, circuit diagrams, and their functional descriptions.

The Infant *Star* 500/950 ventilators have eight major functions that ensure safety and provide flexibility:

- full microprocessor control of gas delivery
- adjustable background-flow ventilation to reduce work of breathing
- automatic correction of inadvertent PEEP
- built-in patient monitoring
- five automatic alarms for tubing obstruction
- data output to a personal computer
- 30 minutes of internal battery power
- updateable software

### 4.1.1 Microprocessor Controlled Gas Delivery System

The Infant *Star* 500/950 ventilator gas-delivery system is microprocessor controlled. The microprocessor and software program precisely shape the flow and amount of pressure delivered to the patient.

The Infant *Star* 500/950 ventilators have solenoid valves. These solenoid valves are pneumatic switches that are electronically controlled. Gas from the blender enters the proportional manifold, where 6 solenoid valves (SV) on the Infant *Star* 500, produce the following liters per minute (Lpm) flow rates:

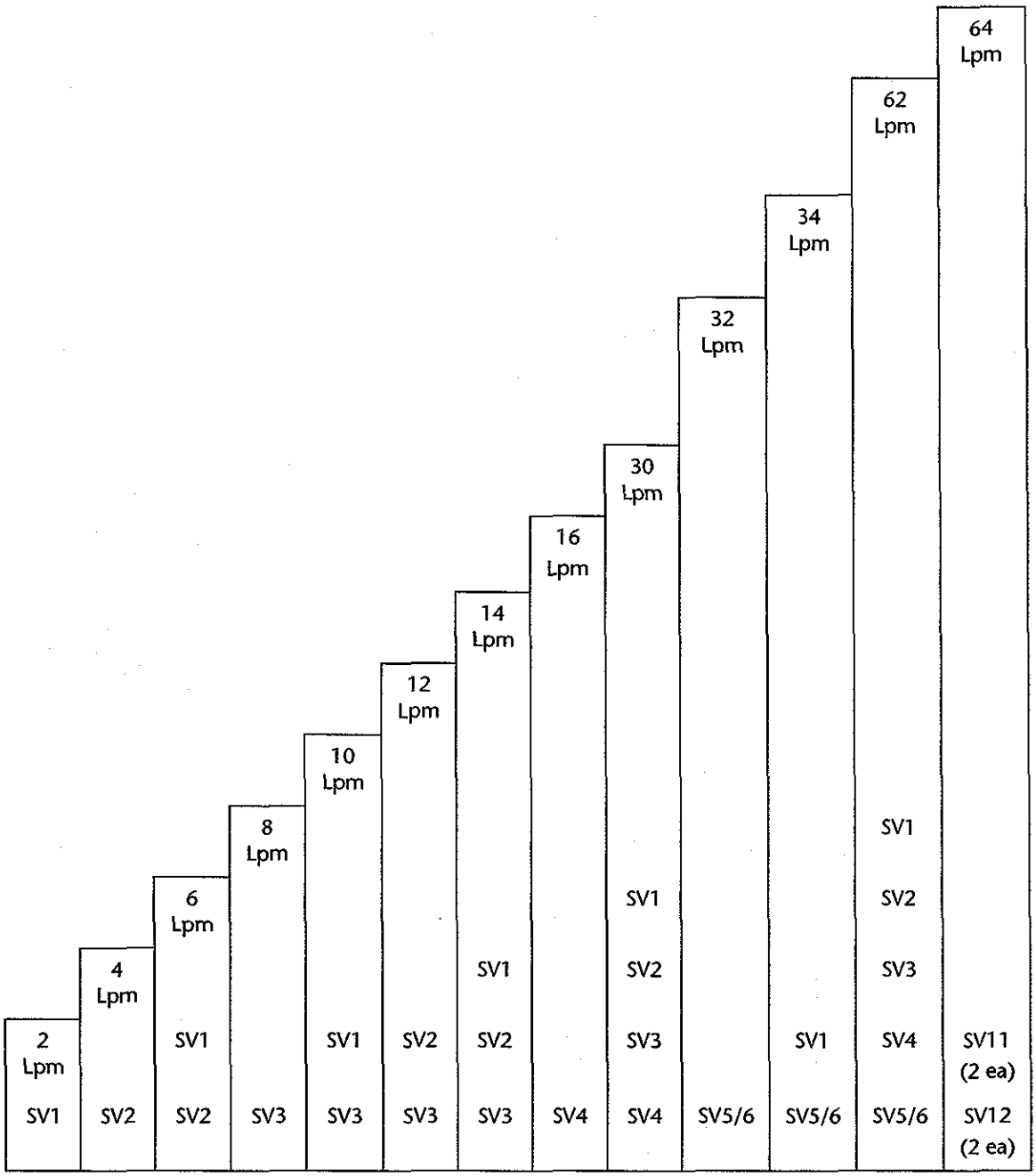
- SV1 = 2 Lpm
- SV2 = 4 Lpm
- SV3 = 8 Lpm
- SV4 = 16 Lpm
- SV5, SV6 = 32 Lpm

To produce the additional flow required by the Infant *Star* 950 for HFV, 4 additional solenoid valves in the proportional manifold operate with the other 6 solenoid valves:

- two SV11 valves A / B and two SV12 valves A / B = 64 Lpm

See Table 4-1 for solenoid combinations to control flow.

**Table 4-1: Solenoid Combinations to Set Flow**




When flow is required, the microprocessor activates one or more solenoid valves.

A mandatory breath is often examined by looking at the proximal airway pressure waveform.

A typical pressure curve is produced by a combination of flow rate, peak inspiratory pressure (PIP), and inspiratory time. The flow rate establishes the angle, or the slope, of the inspiratory pressure waveform for the mandatory breath. A high-flow rate produces a square-shaped waveform, while a lower-flow rate produces a sloped waveform.

In the Infant *Star* 500/950, PIP is an operator-selected value. When flow is established, the gas flow continues at the set rate until the pressure reaches 75% of PIP. At the 75% point, the microprocessor gradually reduces the gas flow, preventing pressure overshoot.

At 10 Lpm (operator-selected value), the flow waveform shows 8, 6, 4 and 2 Lpm and then goes to 0 (zero) flow. Since the endotracheal tube is not cuffed, the 2 Lpm solenoid turns ON and OFF to hold the pressure at the PIP point during the inspiratory plateau. Following inspiration, the exhalation valve opens and expiration occurs immediately. In the Infant *Star* 500/950, the pressure waveform is software modeled to optimize ventilation, regardless of the flow or breaths per minute (bpm) settings.

### 4.1.2 Adjustable Background Flow

The adjustable background flow feature produces a low-level flow of 2 Lpm which is applied as a background flow to eliminate the possibility of rebreathing. A sensitive pressure transducer monitors pressures at the patient's airway. When the patient produces a spontaneous inspiratory effort, the signal is transmitted back to the microprocessor, which then activates one or more solenoids to provide additional gas to the airway (within 30 milliseconds).

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**NOTE:**

For software version 105 and lower, the adjustable background flow can be set up to 30 Lpm For software version 107 and higher, flow can be set up to 32 Lpm. Flow is set in 2 Lpm increments for all software versions.

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With the Infant *Star* 500/950, software versions 105 and lower, additional gas flow is in direct proportion to the patient's effort. For example, if the patient effort produces -1 $cmH_2O$ at the airway, the patient will receive approximately 6 Lpm, a combination of the 2 and 4 Lpm solenoids. An effort of 5 $cmH_2O$ produces up to 34 Lpm. Infant *Star* 500/950 software version 107 or higher has increased the responsiveness of the demand flow system. The demand flow system supplies extra flow to the circuit when the patient's spontaneous breathing exceeds the background flow setting. When the patient effort exceeds 1 $cmH_2O$ for 30 ms, flow is incremental. For every 30 ms that the pressure remains -1 $cmH_2O$, flow is incremented until the sub-baseline pressure is gone or 35 - 40 Lpm flow is reached.

The operator can set flow rates that satisfy the requirements of the mandatory breath, while at the same time, reducing the potential for increased expiratory work of breathing.

### 4.1.3 Inadvertent PEEP Automatic Correction

The combination of the background flow, PEEP/CPAP, and ventilator rate settings (stored in microprocessor) predict the amount of inadvertent PEEP produced.

Based on this prediction, it increases or decreases the ON cycle of a solenoid directing gas flow through the Jet Venturi system which is built into the exhalation valve block. This Jet Venturi system produces a subambient pressure at the expiratory connection of the exhalation leg of the breathing circuit. When the jet flow is increased, more subambient pressure is produced; when it is decreased, there is less subambient pressure. Within 5 seconds of the pressure correction, the microprocessor checks the pressure at the patient's airway and compares that value to the PEEP/CPAP operator-set value. Based on this comparison, automatic compensation occurs until the inadvertent PEEP/CPAP is eliminated.

As the ventilator settings are adjusted, the microprocessor works with the pressure transducer to monitor the patient's airway, make corrections and hold the PEEP/CPAP level constant.

### 4.1.4 Built-In Patient Monitoring

While other systems may require add-on equipment for patient monitoring, the Infant *Star* 500/950 ventilators have a built-in monitoring system.

Digital displays simultaneously show pressure measurements of PEEP/CPAP, mean airway pressure (which is a time weighted average), and PIP. The pressure signal is taken from the infant's airway through the proximal pressure tube to the pressure transducer and then to the microprocessor that does the calculations, integrates them, and controls the display.

The integration of ventilator pressure monitoring reduces the duplication of common components when monitors are purchased separately. This approach also allows us to include 2 pressure transducers: one at the airway and one inside the ventilator. Other systems, using pressure gauges or stand-alone monitors, are vulnerable to undetected high airway pressure caused by disconnection or blockage of the proximal pressure tube. Using two transducers allows a comparison of pressures, alerting the clinician, and preventing undetected high pressure. This system protects against proximal pressure tube blockage, disconnection, or even a single transducer failure. The electronics also work to protect the patient's airway in case of a circuit blockage.

### 4.1.5 Tubing Obstruction Alarms

The operator-set peak inspiratory pressure (PIP) value, programs the microprocessor to limit pressure and compare the set value to what is actually occurring at the airway. Five different detection comparisons are checked, including 3 levels of Pressure Overshoot, the shape of the Expiratory Curve, actual CPAP versus the setting, and high resistance in the inspiratory leg of the breathing circuit. Under all of these conditions, the Infant *Star* 500/950 ventilator systems senses an obstructed tube and reports a specific error message. At the same time, the patient airway is protected from sustained pressure by shutting off gas flow.

- The A01 message indicates high inspiratory pressure (HIP), indicating proximal pressure has reached the HIP setting pressure. If the HIP pressure setting is momentarily reached, gas flow stops, the exhalation valve opens, and the patient airway is vented to PEEP/CPAP. The obstructed tube indicator activates both an audible alarm and visual signal. This type of alarm is most frequently caused by a patient fighting the ventilator, hiccuping, or crying.
- If the exhalation valve opens, but the pressure continues to rise due to a blockage in the expiratory leg of the breathing circuit, a second alarm occurs at HIP +5 $cmH_2O$. An AO2 alarm displays and an audible and a visual signal is activated. When this occurs, the circuit vents through the inspiratory leg of the circuit, thus protecting the patient's airway from sustained pressure.
- A third alarm occurs if something partially blocks the expiratory leg of the breathing circuit and prevents exhalation from occurring quickly. (Under normal operation, PIP drops more than 50% in the first 300 milliseconds.) If something is impeding the patient's exhalation, and pressure is not dropping quickly, the A03 message and an audible alarm activates, indicating elevated expiratory resistance. A complete pneumatic shutdown occurs for 1 second to vent the patient to ambient.
- The A04 message indicates CPAP 6 $cmH_2O$ greater than what has been set, for up to 5 seconds. This can occur when water, tubing fatigue or some other factor is blocking gas flow in the expiratory leg of the breathing circuit. If there is a complete pneumatic shutdown for 3 seconds, the patient is vented to ambient.
- The fifth detection point, A05, indicates a blockage in the inspiratory leg of the circuit or in the proximal pressure line. The ventilator alarms when the internal pressure transducer records a pressure 10 $cmH_2O$ above the set HIP.

Under the A01 alarm condition, the gas delivery stops and both the visual and audible obstructed tube alarms occur. The exhalation valve opens to vent the airway to PEEP. Under the A02, A03 and A04 alarm conditions, gas delivery stops and both the visual and audible

obstructed tube alarms activate. The exhalation valve and the internal vent system open to vent the airway pressure to ambient. This automatic response protects the patient's airway, while the error messages identify the most likely problem.

### 4.1.6 Patient Data Output

Patient data can be sent directly to an IBM compatible personal computer and then to a printer. A Standard RS-232 cable, compatible with all PCs, connects to the output on the back panel of the ventilator. Control settings, airway pressures, and respiratory trending can be automatically recorded.

### 4.1.7 Battery Back Up

The Infant *Star* 500/950 ventilators have a built-in battery backup, and operate on the battery at all times. When connected to an electrical outlet, a self-contained charger keeps the battery at full power. In the event of a power failure, the Infant *Star* 500/950 ventilators continue operating for a minimum of 30 minutes on battery power.

### 4.1.8 Updatable Software

Microprocessor control of display calculations and pneumatics, allows major changes to be made to the software by replacing EPROMs installed on printed circuit boards.

### 4.1.9 Ventilator Functions

The upper module contains the microprocessor electronics and the controls to establish the ventilator parameters.

The lower compartment contains the pneumatics.

Two modes of ventilation are available on the Infant *Star* 500:

- CPAP
- IMV for Infant *Star* 500

Four modes of ventilation are available on Infant *Star* 950:

- CPAP
- IMV
- HFV ONLY
- HFV IMV

Three additional patient-triggered modes are available for both the Infant *Star* 500 and 950 by attaching the *Star Sync* Interface:

- Assist/Control
- SIMV
- CPAP/backup

Dedicated displays identify the control settings:

| | |
|---|---|
| Flow Rate | 4 to 40 Lpm |
| Background Flow | 2 to 30 Lpm (2-32 Lpm 107 software and higher) |
| Ventilator Rate | 1 to 150 bpm |
| Peak Inspiratory Pressure | 5 to 90 $cmH_2O$ |
| Inspiratory Time | 1 to 3 seconds |
| Low Inspiratory Pressure | 3 to 60 $cmH_2O$ |
| HIP Alarm | 5 to 105 $cmH_2O$ |
| PEEP | 0 to 24 $cmH_2O$ |
| Infant *Star* 950 ventilator | additional HFV Rate of 2 to 22 Hz and Amplitude control settings. |

A push-button control allows a single display to be used for observing the I:E ratio, expiration time, or duration of positive pressure.

The three proximal pressure displays provide information about the actual pressure being applied at the patient's airway. The displays include PEEP/CPAP, MEAN Airway Pressure, and PIP.

The intensity of the audible alarm is adjustable. Visual displays show specific alarm violations. The alarm silence button provides a 60-second silence for all violations with the exception of continuous power loss and ventilator inoperative. When an alarm self corrects, the audible part of the alarm automatically stops while the visual indicator continues to provide information on what caused the problem. Pressing the Visual Reset button clears the visual alarm indicator.

Alarms are activated by:

- low inspiratory pressure
- low PEEP/CPAP
- airway leak
- obstructed tube
- insufficient expiratory time
- low oxygen pressure
- high inspiratory pressure
- low air pressure
- external power loss
- low battery
- ventilator inoperative

The lower chamber of the ventilator contains the pneumatic systems, including a mechanical pop-off valve, block assembly (exhalation valve, heater, jet venturi), and oxygen blender control.

The pneumatics base has both air and oxygen inlets on the back panel. Each is protected with water traps and filters. A single outlet provides the blended gas from the operator-set concentration (set via the oxygen control knob). The blended gas may be connected to an accessory flowmeter mounted on a rail system for hand resuscitation or aerosol delivery.

The Infant *Star* 950 has an HFV ON/OFF switch. The rear of the electronics module includes:

- ventilator ON/OFF switch
- hour meter
- RS-232 serial output port for a PC connection
- *Star Sync*™ and remote alarm connector
- analog pressure outputs for connecting to a strip chart recorder
- external battery connection
- circuit breakers
- adjustable baffle for changing the audible alarm intensity

SECTION 5

# Preventive Maintenance

## 5.1 Preventive Maintenance/Extended Test

### 5.1.1 When to Run

Table 5-1 lists the service performed and the Preventive Maintenance/Extended Test and calibration procedure that are performed after service. Run the electrical safety tests, which are a part of the extended test, according to your organization's requirements.

**Table 5-1: Performance Verification Intervals**

| Service Action Performed | Performance Verification Test Requirements |
|---|---|
| **For any service** | Test 5.5.1 |
| **Electronic Section** | |
| Rear Panel Assembly | Tests 5.5.1,20,32 |
| Power Cord | Tests 5.5.1 |
| Hour Meter | Test 5.5.32 |
| Alarm | Tests 5.5.20 |
| ac Circuit Breaker | Tests 5.5.1 |
| **Yoke Assembly** | |
| MP-2 PCA | Test 5.5.32 |
| Analog PCA | Tests 5.5.6,8,9,10,12,20 |
| Alarm Driver (A/D) PCA | Tests 5.5.7,24 |
| Power Supply (P/S) PCA | Tests 5.5.1 |
| Transformer | Tests 5.5.1 |
| 10 V Battery Pack (Ext. Battery Operation) | Test 5.5.31 |
| Front Panel (Infant *Star* 500) | Tests 5.5.6,8,9,10,12,20 |
| Front Panel (Infant *Star* 950) | Tests 5.5.6,8,9,10,12,20,26 |
| Analog Meter | Adjust R76 - Gain Adjust, Test 5.5.6 |

**Table 5-1: Performance Verification Intervals (continued)**

| Service Action Performed | Performance Verification Test Requirements |
|---|---|
| **Pneumatic Section** | |
| High Pressure Gas Filter Assembly | R8 Regulator adjustment, Test 5.5.7 |
| Air Regulator Assembly | Tests 5.5.4,5,7,15 |
| Oxygen Regulator Assembly | Oxygen Regulator Calibration, Tests 5.5.4,5,7,15 |
| Oxygen Blender Assembly | Oxygen Blender Calibration, Tests 5.5.7,15 |
| Proportional Flow Manifold (Infant *Star* 500) | Tests 5.5.4,7,19,22.1 |
| Proportional Flow Manifold (Infant *Star* 950) | Tests 5.5.4,7,19,22.1,26,27,28 |
| IMV Regulator Assembly | Verify output, Test 5.5.9 |
| PEEP Regulator Assembly | Test 5.5.13 |
| Mini Regulator | Verify output is 13 psi,Tests 5.5.4,13 |
| Transducer PCA | Tests 5.5.4,7,19,22.1,26,27,28 |
| SV8 PEEP, SV9 Venturi Solenoids (Infant *Star* 500) | SV8 - PEEP Calibration, Tests 5.5.13,14 |
| SV8 PEEP, SV9 Venturi Solenoids (Infant *Star* 950) | SV8 - PEEP Calibration, Tests 5.5.13,14,26 |
| SV7 Safety Vent Valve Solenoid | Test 5.5.22.1 |

## 5.2 Test Equipment and Service Material Required

The tools listed in Table 5-2 are required for total performance verification and calibration. Refer to specific tests for individual tool requirements.

**Table 5-2: Test Equipment Tools**

| | |
|---|---|
| Gauge, Capsuhelic -5 - +5 $cmH_2O$ (P/N – N-4300010) | |
| *PTS 2000* (or equivalent) OR RT200 | |
| Adjuster Tool, Oxygen Regulator (P/N – N-97101016) | |
| Tee Assembly, (2 required) (P/N – N-9710161) | |
| **Manometers: (or equivalent)**<br>0 to 100 $cmH_2O$<br>Accuracy: ±1% of full scale<br>0 to 10 $cmH_2O$ (Positive or Negative Pressure)<br>Accuracy: ±1% of full scale | |
| Flowmeter: | 0 to 200 Lpm, Float or Ball type. Dwyer RMC 103 (or equivalent) |
| Flowmeter: | 0 to 50 Lpm, Float or Ball type. Dwyer RMC 101 (or equivalent) |
| Oxygen Analyzer: | MiniOx 3000 (or equivalent) |
| Tubing: | 1/8 in., and 10 mm, as required |
| Syringe: | 50 ml |
| Tee Adapter: | 1/8 in. pneumatic |

For 950 HF

**Table 5-2: Test Equipment Tools (continued)**

| | |
|---|---|
| Tee Adapter: | 10 mm pneumatic |
| Adapter: | 1/8 in. to 10 mm |
| Frequency Counter (use Fluke Volt Meter) for Infant *Star* 950 HFV Rate | |
| Digital Volt Meter: | 3-1/2 Digit Fluke 87 or similar |
| **Patient Circuit:** | |
| Standard circuit: | P/N – N-501011 (Infant *Star* 500/950) |
| HFV circuit: | P/N – N-501023 (Infant *Star* 950) |
| Infant *Star* Test Lung: | P/N – N-1101262 |
| Rubber Test Lung: | P/N – 4-000612-00 (or similar) |
| Analyzer: | Electrical Safety |
| **Regulators:** | |
| With gauge 0 - 50 psi air supply | |
| With gauge 0 - 50 psi oxygen supply | |
| Static Control System | |
| **Miscellaneous Supplies (or equivalent)** | |
| Isopropyl Alcohol for cleaning | |
| Cotton Swabs | |
| Loctite Adhesive Sealant, #271, Red | |
| GE RTV 118 Silicone | |
| Torque Seal | |
| Devcon 14210 5-Minute Epoxy | |
| Dow Corning 340 Silicone Heat Sink Compound | |
| Fisher & Paykel low compressible volume humidifier chamber (P/N – N-501209) | |

## 5.3 Preliminary Ventilator Cleaning and Inspection

To prevent disease transmission, use personal protective equipment when handling contaminated bacterial filters or other patient accessories.

**NOTE:**

If any problems are found during the preliminary inspection, correct them before proceeding with the performance verification. The failure to correct such problems now may affect the remainder of the performance verification.

Clean and inspect the ventilator for obvious problems such as missing broken parts, loose assemblies or disconnected wires, connectors or tubing. Repair as needed.

## 5.4 Preliminary Ventilator Set Up

Set up the ventilator for the Extended Test:

1. Install a complete infant circuit and Infant *Star* test lung:
   - P/N – N-501011 for the Infant *Star* 500/950 patient circuit
   - P/N – N-501023 for the Infant *Star* 950 HFV patient circuit
   - P/N – N-501209 for the Fisher & Paykel low compliance humidifier chamber
   - P/N – N-1101262 for the Infant *Star* test lung
2. Connect the ventilator to both an air and oxygen source. (Ventilator hour meter reading should be observed at this time.)

## 5.5 Preventive Maintenance/Extended Test Procedure

To ensure systematic performance verification and logical fault diagnosis, perform these tests in the order given. If a test must be repeated, the current control settings are completely defined at the beginning of each test procedure.

**NOTE:**

- If running the performance verification tests in the order written, only the **boldface** ventilator settings must be changed.
- If a test fails, identify the cause of a malfunction by noting the item number at the end of the step; then refer to that item number in Section 5.6. Perform tasks in the referenced item to identify and correct the causes of malfunctions.

Follow these general guidelines when running the performance verification:

- If a problem occurs during the performance verification, check to verify that the procedures were correctly performed before attempting to repair the ventilator.
- Verify all data entered.
- Use alarm silence and alarm reset keys to restore the ventilator to the test condition. Using these keys may be necessary because of the nonstandard set of conditions that may cause an alarm condition to occur.
- When making ventilator settings, be aware that because of the inter-relationship between some ventilator settings, you may not always be able to make all settings in the indicated sequence.
- Except for the alarm silence and alarm-reset keys, do not change the control settings during these procedures, unless specifically instructed.
- When repairs are completed, repeat the test. When the test is successful, proceed with the next test, as applicable.

**Warning**

Follow accepted safety procedures for electrical equipment when making connections, adjustments, or repairs.

### 5.5.1 Electrical Safety Test

**Warning**

If the ventilator fails an electrical safety test, do not proceed to the next electrical safety test until the problem is corrected and the test is repeated.

**NOTE:**

There are no specific ventilator setting requirements for the electrical safety test.

1. Make sure the unit is turned OFF.
2. Verify ground resistance is 0.1 Ω or less (See Section 5.6, item 1.)
3. Turn ON the ventilator.
4. Verify that forward and reverse current leakage to ground is 25 mA on 115 Vac units and 40 mA on 220 Vac units. (See Section 5.6, item 2.)

### 5.5.2 Power-On Self Test

1. Turn ON the power switch.
2. Set the unit to the following Standard Test Conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| **PEEP/CPAP** | **Fully counterclockwise** |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **4 Lpm** |
| **Ventilator Rate** | **30 bpm** |
| **Peak Inspiratory Pressure** | **40 $cmH_2O$** |
| **High Inspiratory Pressure** | **45 $cmH_2O$** |
| **Inspiratory Time** | **1.0 second** |
| **Low Inspiratory Pressure** | **30 $cmH_2O$** |
| **Display Select** | **Expiration Time** |
| **Oxygen Percent** | **60** |
| **Pressure Relief Valve** | **Fully clockwise** |
| **HFV Rate** | **12 Hz** |
| **HFV Amplitude** | **Fully clockwise 3 - 4 turns (no hard stop)** |

3. Verify that all displays illuminate (except Low Battery and Ext Power Loss). Vent Inop may blink at initial power-up. The software level momentarily appears in the Selected Data window. (See Section 5.6, item 3.)

### 5.5.3 A05 Test (High Peak Inspiratory Pressure)

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 30 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Disconnect To Patient tube at manifold and block the connector on the bottom of the Pressure Relief valve.

3. Verify HI-PIP, A05, Obstructed Tube and Low Inspiratory Pressure Alarms and Displays. (See Section 5.6, item 4.)
4. Reconnect tube, allow audible alarm to self-cancel, then push Visual Reset.
5. Set the following test conditions:

| | |
|---|---|
| **Mode** | **CPAP** |
| **PEEP/CPAP** | **10 $cmH_2O$** |
| **Flow Rate** | **8 Lpm** |
| **Background Flow** | **8 Lpm** |

6. Verify that PEEP/CPAP reads 10 $cmH_2O$ in the following four displays:
   - Proximal Airway Pressure gauge
   - PEEP/CPAP window
   - MEAN Pressure window
   - PEEP/CPAP setting display
7. After checking at 10 $cmH_2O$, reset PEEP/CPAP to 20 $cmH_2O$, and again verify displays. (See Section 5.6, item 4.)

### 5.5.4 Low Air and Low Oxygen Pressure Switch Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | CPAP |
| **PEEP/CPAP** | **Fully counterclockwise** |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **4 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 30 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

**NOTE:**
If using a *PTS 2000*, the HIGH PRESSURE function is required for the measurements in this section; all readings are the "current" reading.

2. Reduce air pressure to 40 psi.
3. Verify that the Low Air Pressure alarm is ON.
4. Raise the air pressure to 45 psi.
5. Verify that the Low Air Pressure alarm is OFF. (See Section 5.6, item 5.)

6. Repeat steps 2 - 5 for oxygen pressure. (See Section 5.6, item 6.) Ensure that the Safety Vent Valve does not open.

### 5.5.5 Check Valve Test

1. Set up the ventilator as follows:

| Mode | IMV |
|---|---|
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 30 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Disconnect air and oxygen high-pressure hoses alternately at the ventilator, and ensure that there is no leakage from the connection while the other gas system is applying pressure.
3. To test the check valves, insert the disconnected end of the high-pressure hose into a cup of water.
4. If there are more than fifty bubbles in 10 seconds, the leak is significant and the check valve should be replaced. (See Section 5.6, item 7.)

### 5.5.6 Proximal Pressure Calibration

1. Set the following test conditions:

| Mode | CPAP |
|---|---|
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 30 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude *x* | Fully clockwise 3-4 turns (no hard stop) |

2. Auto-Zero the ventilator by disconnecting the proximal airway pressure line and power the ventilator OFF, then ON, 3 times.
3. Verify that the proximal airway meter and the PEEP/CPAP display read 0 $cmH_2O$ ±0.50. (See Section 5.6, item 8.)
4. Using the *PTS 2000* (or equivalent), tee a syringe to the + low-pressure port and the proximal airway pressure line.
5. Apply pressure, using a syringe, until the desired pressure is displayed.

| Apply ($cmH_2O$) | Measure Limits |
|---|---|
| 5 | 4 to 6 |
| 25 | 24 to 26 |
| 50 | 48 to 52 |
| 75 | 73 to 77 |
| 95 | 92 to 98 |

6. Verify that the PEEP/CPAP display and Analog meter readings are within specifications. (See Section 5.6, item 8.)
   Ignore the Obstructed Tube Alarm during this test.
7. When the ventilator digital readings are verified as correct, it will not be necessary to use an external pressure gauge in future tests.

### 5.5.7 Background Flow Control Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | CPAP |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **40 Lpm** |
| **Background Flow** | **See below** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 30 $cmH_2O$ |
| Display Select | Expiration Time |
| **Oxygen Percent** | **21** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

**NOTE:**
The background control increments at 2 Lpm (2 - 30 Lpm for software version 105 or lower) and (2 - 32 Lpm for software version 107 or higher).

2. Using the *PTS 2000* (or equivalent), measure the flow from the To Patient port against the values listed in the chart below. Use the Air and High Flow function to take the current reading. (See Section 5.6, item 9.)
3. If running software 107, disconnect the proximal airway pressure line.

**NOTE:**

- The flow rate must be set higher than, or equal to, the background flow.
- The proximal PEEP must read 0 (zero) for the flow measurement to be accurate.

Disconnect Prox airway press Tubing

| Background Flow Rate Control (Lpm) | Measure Limits (Lpm) |
|---|---|
| 2 | 1.8 to 2.2 |
| 4 | 3.6 to 4.4 |
| 8 | 7.2 to 8.8 |
| 16 | 14.4 to 17.6 |
| 30 | 27.0 to 33.0 |
| 32 | (Software 107 or higher) 28.8 to 35.2 |

## 5.5.8 Ventilator Rate Control Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **4 Lpm** |
| **Ventilator Rate** | **See below** |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 30 $cmH_2O$ |
| Display Select | Expiration Time |
| **Oxygen Percent** | **60** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise **3 - 4** turns (no hard stop) |

2. Verify that Ventilator Rate display increments:
   - Between 1 and 60, the unit increments in 1 bpm steps.
   - Between 60 and 130, the unit increments in 2 bpm steps.
   - Between 130 and 150, the unit increments in 5 bpm steps.
3. Set VENT RATE to 30 bpm, and measure the time for 15 breaths. Test Limits: 29 to 31 seconds. (See Section 5.6, item 10.)

### 5.5.9 Peak Inspiratory Pressure

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **See below** |
| **Background Flow** | **See below** |
| Ventilator Rate | 30 bpm |
| **Peak Inspiratory Pressure** | **See below** |
| **High Inspiratory Pressure** | **105 $cmH_2O$ (blinking)** |
| Inspiratory Time | 1.0 second |
| **Low Inspiratory Pressure** | **3 $cmH_2O$** |
| Display Select | Expiration Time |
| **Oxygen Percent** | **21** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise **3 - 4** turns (no hard stop) |

2. Check that PIP increments in 1 $cmH_2O$ steps, from 5 to 90.
3. Using the chart below set the PIP and Flow Rate. Set Background Flow to 4 Lpm. Repeat the test using a Background Flow of 20 Lpm. (See Section 5.6, items 11, 12.)

| PIP ($cmH_2O$) | Flow Rate (Lpm) | Background Flow (Lpm) | PIP Limits ($cmH_2O$) |
|---|---|---|---|
| 10 | 20 | 4 then 20 | 9 to 11 |
| 20 | 20 | 4 then 20 | 18 to 22 |
| 40 | 20 | 4 then 20 | 38 to 42 |
| 60 | 20 | 4 then 20 | 58 to 62 |
| 80 | 20 | 4 then 20 | 78 to 82 |
| 20 | 10* | 4 only | 18 to 22 |

**NOTE:**
If the difference between the PEEP/CPAP and PIP settings is < 5 $cmH_2O$, the ventilator will not accept the PIP setting and the PIP value display will blink. Perform the steps below to verify this range.

4. Set PEEP/CPAP to 10 $cmH_2O$.
5. Set PIP to 14 $cmH_2O$ (PIP value should blink).
6. Adjust PIP to 18 $cmH_2O$ (PIP value should stop blinking).

### 5.5.10 Inspiratory Time Control Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| **PEEP/CPAP** | **Fully counterclockwise** |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **4 Lpm** |
| **Ventilator Rate** | **15 bpm** |
| **Peak Inspiratory Pressure** | **40 $cmH_2O$** |
| **High Inspiratory Pressure** | **45 $cmH_2O$** |
| **Inspiratory Time** | **See below** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| **Oxygen Percent** | **60** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise **3 - 4** turns (no hard stop) |

2. Verify the Inspiratory Time display increments:
   - 1 step between 0.10 to 0.60 seconds
   - 2 steps between 0.60 to 1.0 seconds
   - 10 steps between 1.0 to 3.0 seconds
3. Set mode:

| | |
|---|---|
| **Ventilator Rate** | **30 bpm** |
| **Inspiratory Time** | **1.0 seconds** |

Observe the Expiratory Time in the Selected Data window while measuring the Inspiratory Time at the Analog Output connector on the rear cover of unit (pins 1 and 3).

**NOTE:**
If using a DVM for the next two measurements, first verify the frequency is 0.5 Hz, then verify the duty cycle is between 40% and 60%. USE J18 on Alarm Driver Board

4. Verify the Expiratory Time display reads 1.0 seconds. (See Section 5.6, item 13.)
5. Verify the Inspiratory Time reads between 0.95 to 1.1 second on the measurement device. (See Section 5.6, item 13.)

### 5.5.11 Duration of Positive Pressure Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | **Duration of Positive Pressure** |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Verify the duration of positive pressure reads between 1.13 and 1.19 in the Selected Data window. (See Section 5.6, item 14.) Most units 1.12 - 1.13

### 5.5.12 Expiratory Time and I:E Ratio Display Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **10 Lpm** |
| Background Flow | 4 Lpm |
| **Ventilator Rate** | **See below** |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| **Inspiratory Time** | **0.4 second** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | **Expiration Time** |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Using the following chart, adjust the Ventilator Rate and verify the Expiration Time display and Insufficient Expiration Time alarm. (See Section 5.6, item 15.)

| Ventilator Rate (bpm) | Expiration Time (seconds) | Insufficient Expiration Time Alarm |
|---|---|---|
| 1 | 59.6 | OFF |
| 62 | 0.57 | OFF |
| 88-98* | 0.30 | ON |
| 100 | 0.20 | OFF |
| 102-150* | 0.20 | ON |

*Ventilator rate settings will blink during test.

3. Change Data Select to I:E Ratio.
4. Adjust Ventilator Rate and verify that the I:E Ratio display corresponds to: (See Section 5.6, item15.)

| Ventilator Rate (bpm) | I:E Ratio |
|---|---|
| 1 | 1:99.9 blinks |
| 6 | 1:24.0 |
| 33 | 1:3.5 |
| 102-150 | 1:--- |

### 5.5.13 PEEP/CPAP Control Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | CPAP |
| **PEEP/CPAP** | **See below** |
| Flow Rate | 40 Lpm |
| **Background Flow** | **See below** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | **1.0 second** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Verify the Proximal Airway meter and, while turning the PEEP/CPAP knob, verify that the PEEP/CPAP Range includes 0 to 20 $cmH_2O$ ±1. (In most cases PEEP will go to 24 $cmH_2O$ maximum, but 20 $cmH_2O$ is acceptable.)

3. Adjust Background Flow and PEEP/CPAP setting according to the table below.
4. Verify the PEEP/CPAP Proximal Display for 5 seconds after stabilization, and ensure that PEEP/CPAP setting, and the PEEP/CPAP values are within their specified ranges. (See Section 5.6, item 17.)

Calibrate Venturi if High

| Background Flow (Lpm) | PEEP/CPAP Level ($cmH_2O$) | Range |
|---|---|---|
| 4 | 0 | ±1 |
| 4 | 2 | ±1 |
| 4 | 6 | ±1 |
| 4 | 15 | ±1 |
| 4 | 20 | ±1 |
| 20 | 2 | ±1 |
| 20 | 6 | ±1 |
| 20 | 15 | ±1 |
| 20 | 20 | ±1 |
| 30 | 2 | ±2 |
| 30 | 6 | ±2 |
| 30 | 15 | ±2 |
| 30 | 20 | ±2 |

5. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| **PEEP/CPAP** | **Fully counterclockwise** |
| Flow Rate | 40 Lpm |
| **Background Flow** | **See below** |
| **Ventilator Rate** | **See below** |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| **Inspiratory Time** | **See below** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

6. Set Background Flow, Inspiratory Time, and Ventilator Rate values shown in the table below; then verify that PEEP/CPAP display reads less than the maximum allowed. (See Section 5.6, item 17.)

| Flow Rate (Lpm) | Background Flow Lpm) | Inspiratory Time (seconds) | Ventilator Rate (bpm) | Maximum Allowed PEEP/CPAP ($cmH_2O$) |
|---|---|---|---|---|
| 40 | 30 | 0.50 | 60 | 5 |
| 30 | 30 | 0.33 | 90 | 2 |
| 20 | 20 | 0.15 | 120 | 2 |
| 10 | 10 | 0.10 | 150 | 2 |

### 5.5.14 Oxygen Blender Test

1. Blender Dial Alignment:
   a. Turn the $O_2$ control knob fully counterclockwise.
   b. Check that the mark on the $O_2$ control knob aligns with the 21 percent mark on the console base. (Mark is considered aligned if any part of one mark makes contact with the other.)
   c. Turn $O_2$ control knob fully clockwise.
   d. Check that the mark on the $O_2$ control knob aligns with the 100 percent mark on the console base. (Mark is considered aligned if any part of one mark makes contact with the other.)
2. With air and oxygen connected to the ventilator, connect the ventilator To Patient port to the High Flow port on the *PTS 2000* (or equivalent). Take readings in the % Oxygen and current function.
3. Set the following test conditions:

| | |
|---|---|
| **Mode** | **CPAP** |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **See below** |
| **Ventilator Rate** | **30 bpm** |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| **Inspiratory Time** | **1.0 second** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration time |
| **Oxygen Percent** | **See below** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

4. With the ventilator connected to air and oxygen supply, attach a calibrated oxygen analyzer to the To Patient port, leaving one side of the analyzer's sensor with a 12-inch tube open to atmosphere. (See Section 6, Figure 6-6.)
5. If the ventilator has software 107 installed, disconnect the proximal airway pressure line and zero the Pressure Transducer PCA.→Nit Alarm Silence
6. Set Background Flow to 16 Lpm and verify readings. (See Section 5.6, item 18.)
7. Repeat the test at 4 Lpm.

| Oxygen Percent | Measured Value |
|---|---|
| 21 | 21 to 22 |
| 30 | 27 to 33 |
| 60 | 57 to 63 |
| 90 | 87 to 93 |
| 100 | 99 to 100 |

### 5.5.15 Oxygen Blender Potentiometer Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | **I:E Ratio** |
| **Oxygen Percent** | **60** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

**Caution**

Be sure to perform this test while unit is plugged into ac power. Performing this test using battery power may give erroneous readings.

2. Be sure to perform this test while unit is plugged into ac power. Performing this test under battery power may give erroneous readings.
3. Verify: Diagnostics window 2 displays the Oxygen Blender Potentiometer setting. It should read ±3% of what the $O_2$ control knob indicates. (See Section 5.6, item 19.)
4. To adjust the displayed value, loosen the Allen screw on the white gear on the potentiometer.

5. By pulling the white gear forward, the shaft of the Potentiometer can be rotated to display the appropriate number in the diagnostic window.
6. Push the white gear to its original position on the shaft and tighten Allen screw.

### 5.5.16 Crossover Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **40 Lpm** |
| **Background Flow** | **30 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | **Expiration Time** |
| **Oxygen Percent** | **21** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise **3 - 4** turns (no hard stop) |

2. Using a *PTS 2000* (or equivalent), measure high-pressure readings using the current reading for the High Pressure function.
   a. Set air line pressure to 75 psig (or maximum possible considering environmental conditions).
   b. Set oxygen line pressure to 40 psig.
3. Using the same test setup as in 5.5.15, verify that oxygen concentration does not rise above 22%. (Ignore the LOW $O_2$ Alarm.) (See Section 5.6, item 20.)

### 5.5.17 Air/Oxygen Crossover Network Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **CPAP** |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 40 Lpm |
| Background Flow | 30 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| **Oxygen Percent** | **60** |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise **3 - 4** turns (no hard stop) |

2. Disconnect the Proximal Airway Pressure line.
3. Using a *PTS 2000* (or equivalent), connect a hose between the High Flow port and the To Patient port on the ventilator.
4. Set the Flow Rate to 40 Lpm and Background Flow to 30 Lpm.
5. Disconnect air pressure source and allow ventilator to stabilize for approximately 10 seconds.
6. Verify the High Flow reading is > 26 Lpm. (See Section 5.6, item 21.)
7. Reconnect air source, allow ventilator to stabilize.
8. Disconnect the oxygen pressure source and allow the ventilator to stabilize.
9. Verify the High Flow reading is > 26 Lpm. (See Section 5.6, item 21.)
10. Reconnect the oxygen pressure source.

### 5.5.18 Blended Gas Outlet Test

1. Turn Ventilator Power OFF.
2. Using the *PTS 2000* (or equivalent), connect a hose between the High Pressure port and the blended-gas port on the ventilator. - Back of Unit
3. Verify the current pressure is 18 psi ±1 psi. (See Section 5.6, item 22.)
4. Using the *PTS 2000* (or equivalent), connect a hose between the High Flow port and the ventilator blended-gas port.
5. Verify the Blended Gas Outlet reads between 18 and 22 Lpm (or ±10% of the value stated on label). (See Section 5.6, item 22.)

### 5.5.19 Low Inspiratory Pressure Alarm, Audible and Alarm Silence Tests

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **4 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| **Low Inspiratory Pressure** | **See below** |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Check that Low Inspiratory Pressure changes are in increments of 1 $cmH_2O$ between 3 and 60 $cmH_2O$, and the readings are stable. (Ignore alarm.)
3. Set the Low Inspiratory Pressure to 42 $cmH_2O$.
4. The Low Inspiratory Pressure alarm should activate. (See Section 5.6, item 23.)
5. Press ALARM SILENCE.
6. Verify that ALARM SILENCE period equals 1 minute (±3 sec.)
7. Press ALARM SILENCE twice.
8. Verify that Audible turns OFF and back ON. (See Section 5.6, item 23.)
9. Open Volume Control baffle.
10. Verify loud "beeps" (back panel) and low steady tone (alarm driver PCA). (See Section 5.6, item 23.)
11. Close the baffle and verify that the alarm signal is audible from a distance of six feet, while facing the front of the ventilator.
12. Reduce the Low Inspiratory Pressure Alarm setting to 28 $cmH_2O$.
13. Verify that audible alarm turns OFF, and Low Inspiratory Pressure LED stays ON until Visual Reset button is pressed. (See Section 5.6, item 23.)

### 5.5.20 Low PEEP/CPAP Alarm Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **CPAP** |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| **Background Flow** | **10 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| **Low Inspiratory Pressure** | **3 $cmH_2O$** |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Disconnect the hose from the proximal airway pressure inlet on the front of the pneumatics unit.
3. Connect a syringe to the proximal airway pressure inlet fitting; adjust the syringe pressure to zero PEEP/CPAP.

4. Perform the following steps for each PEEP/CPAP setting listed below:

| PEEP/CPAP Setting ($cmH_2O$) | Alarm ON ($cmH_2O$) | Alarm OFF ($cmH_2O$) |
|---|---|---|
| 0 | -2 | -1 |
| 2 | 0 | 1 |
| 6 | 3 | 4 |
| 9 | 5 | 6 |
| 13 | 8 | 9 |
| 20 | 15 | 16 |

5. Set syringe pressure (as shown on the PEEP/CPAP display setting) to the Alarm Off pressure setting.
6. Verify that the Low PEEP/CPAP alarm is OFF. (See Section 5.6, item 24.) If the alarm is ON, wait (up to 25 seconds) for the alarm to turn OFF, then press the Visual Reset button to clear the LED.
7. Decrease the syringe pressure to the alarm on setting (ignore the airway-leak alarm).
8. Verify that the low PEEP/CPAP Pressure Alarm activates within 30 seconds, and takes 20 seconds to deactivate. (See Section 5.6, item 24.)

### 5.5.21 Obstructed Tube Alarm Tests

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| **PEEP/CPAP** | **Fully counterclockwise** |
| Flow Rate | 20 Lpm |
| **Background Flow** | **4 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Crimp the tube at the test lung and verify HIGH PIP alarm. PIP should be > 40 $cmH_2O$, but not higher than 50 $cmH_2O$ in the proximal airway digital display. Usually over 60
3. Remove crimp.
4. Squeeze the lung when the breath reaches peak pressure.
5. Verify that the unit can display HI PP A01, A02 (unit may not display the A02 alarm) and A05 alarms. (See Section 5.6, item 25.)

6. Kink the From Patient line hard enough to diminish flow and activate Obstructed Tube Alarm (HI PIP A03).
7. Verify that the Proximal Pressure drops abruptly when the alarm activates. Continue to kink the From Patient tube to activate a HI PP A04. (See Section 5.6, item 25.)

### 5.5.22 High CPAP Alarm Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **CPAP** |
| **PEEP/CPAP** | **10 $cmH_2O$** |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Turn Ventilator OFF.
3. Connect a syringe to the Proximal Airway Pressure inlet.
4. Turn Ventilator ON.
5. Increase syringe pressure until OBSTRUCTED TUBE (HI CP A04) Alarm activates.
6. Log the highest PEEP/CPAP display reading before the alarm activates (Test Limits: 15 to 25 $cmH_2O$). (See Section 5.6, item 26.)

Normally alarms at 16

### 5.5.23 Overpressure Pressure Relief Valve Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| **PEEP/CPAP** | **Fully counterclockwise** |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| **Ventilator Rate** | **12 bpm** |
| **Peak Inspiratory Pressure** | **90 $cmH_2O$** |
| **High Inspiratory Pressure** | **95 $cmH_2O$** |
| **Inspiratory Time** | **3.0 second** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |

If pressure will not hold Reg 5 (IMV) may not be set to 62 cm $H_2O$.

Check by removing outlet tubing from bottom of reg & put in extension tube & check low Pressure on meter. To adjust Remove top of reg & adjust w screwdriver

| | |
|---|---|
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Turn the Relief Valve adjustment counterclockwise and note the Relief Valve setting on the PIP display. (Ignore alarms.)
3. Increase the adjustment, and verify that it can be adjusted from 12 to 90 $cmH_2O$. (See Section 5.6, item 27.)

### 5.5.24 Vent Inop Test

1. Set the following test conditions:

| | |
|---|---|
| Mode | IMV |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| **Ventilator Rate** | **30 bpm** |
| **Peak Inspiratory Pressure** | **40 $cmH_2O$** |
| **High Inspiratory Pressure** | **45 $cmH_2O$** |
| **Inspiratory Time** | **1.0 second** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Remove the rear cover of ventilator head.
3. Disconnect J9 connector at the Analog PCA.
4. Verify that Vent Inop condition occurs. (See Section 5.6, item 28.)
5. Reconnect J9 connector.
6. Verify that the Vent Inop does not deactivate. If the Vent Inop does deactivate, the Alarm Driver PCA may have malfunctioned. (See Section 5.6, item 28.)
7. Switch the ventilator main power switch OFF and ON.
8. Verify normal conditions.
9. Disconnect J14 at the I/O PCA and repeat the procedure.

### 5.5.25 Airway Leak Alarm Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **CPAP** |
| **PEEP/CPAP** | **Fully counterclockwise** |
| Flow Rate | 20 Lpm |
| **Background Flow** | **8 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully clockwise 3 - 4 turns (no hard stop) |

2. Disconnect the To Patient tube.
3. Turn PEEP/CPAP control clockwise to 3 $cmH_2O$.
4. Verify that the leak alarm activates within five seconds. (See Section 5.6, item 29.)

### 5.5.26 HFV Rate Control Calibration and Test (Infant *Star* 950)

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **HFV ONLY** |
| PEEP/CPAP | Fully counterclockwise |
| Flow Rate | 20 Lpm |
| **Background Flow** | **4 Lpm** |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| **HFV Rate** | **12 Hz** |
| **HFV Amplitude** | **Fully clockwise 3 - 4 turns (no hard stop)** |

2. Using a storage oscilloscope or a frequency counter, observe the Proximal Airway pressure waveform. The measurement should be taken from the rear panel, on the Analog Output 3-pin Din connector pins (1 positive and 3 negative).
3. Remove the HFV Rate knob. While viewing the measurement device, adjust the HFV RATE shaft until the time from HFV pulse to HFV pulse equals 0.250 seconds.
4. Install the knob so that the indicator points to 4 Hz.
5. Adjust the following HFV RATE settings and record the time from HFV pulse to HFV pulse. Verify it to be within the specified limits listed below. (See Section 5.6, item 30.)

| HFV Rate Setting (Hz) | HFV Rate Limits (seconds) (±10%) | Infant *Star* 950 HFV Rate (Hz) |
|---|---|---|
| 10 | 0.090 to 0.110 | 9.09 to 11.11 |
| 14 | 0.064 to 0.079 | 12.66 to 15.62 |
| 20 | 0.045 to 0.055 | 18.18 to 22.22 |

## 5.5.27 HFV Flow Test (Infant *Star* 950)

**NOTE:**

This procedure is based on using the Mallinckrodt:

- high frequency breathing circuit (P/N – N-501011)
- standard test lung (P/N – N-1101262)

1. Connect a ball-type flowmeter (or equivalent) in series with the To Patient tube.
2. Set the following test conditions:

| | |
|---|---|
| Mode | HFV ONLY |
| **PEEP/CPAP** | **24 $cmH_2O$** |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| **HFV Rate** | **12 Hz** |
| **HFV Amplitude** | **Fully counterclockwise 3 - 4 turns (no hard stop)** |

3. Verify that the flow is between 6 and 13 Lpm. (See Section 5.6, item 31.)
4. Slowly turn the HFV Amplitude clockwise. Verify the flowmeter bouncing ball is normal and that the flow increases as the knob is rotated clockwise.
5. Set the HFV Amplitude fully clockwise.
6. Set the HFV Rate to 14 Hz.
7. Verify that the HFV Flow is between 34 – 43 Lpm. (See Section 5.6, item 31.)
8. Remove the flowmeter.

### 5.5.28 HFV Amplitude Test (Infant *Star* 950)

1. Install the HFV Breathing Circuit for this test.
2. Set the following test conditions:

| | |
|---|---|
| Mode | HFV ONLY |
| **PEEP/CPAP** | **Fully counterclockwise** |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| **HFV Rate** | **12 Hz** |
| **HFV Amplitude** | **Fully counterclockwise 3 - 4 turns (no hard stop)** |

3. Verify that the HFV Amplitude display is between 6 - 12 $cmH_2O$. (See Section 5.6, item 32.)
4. Set the HFV Amplitude fully clockwise and the Rate to 14 Hz.
5. Verify that the HFV Amplitude display is between 42 and 64 $cmH_2O$. (See Section 5.6, item 32.)

## 5.5.29 HFV PEEP/CPAP Control Test (Infant *Star* 950)

**NOTE:**

This procedure is based on using the Mallinckrodt:

- High frequency breathing circuit (P/N – N-501011)
- Fisher & Paykel low compressible volume humidifier chamber (P/N – N-501209)
- Standard test lung (P/N – N-1101262)

1. Set the following test conditions:

| | |
|---|---|
| Mode | HFV ONLY |
| **PEEP/CPAP** | **See below** |
| Flow Rate | 20 Lpm |
| Background Flow | 4 Lpm |
| Ventilator Rate | 30 bpm |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| Inspiratory Time | 1.0 second |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | **I:E Ratio** |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| **HFV Rate** | **12 Hz** |
| **HFV Amplitude** | **Fully counterclockwise 3 - 4 turns (no hard stop)** |

2. Adjust PEEP/CPAP settings as listed below.
3. Verify the PEEP/CPAP setting and the PEEP/CPAP display agree for at least 5 seconds before recording the Servo Correction. (See Section 5.6, item 33.)
4. To view the Servo Correction, press and hold both the Alarm Silence and Visual Reset buttons until ":--1" appears in the Selected Data window.

| PEEP/CPAP ($cmH_2O$) | Limits ($cmH_2O$) |
|---|---|
| 3 | -16 to +16 |
| 4 | -16 to +16 |
| 6 | -16 to +16 |
| 8 | -16 to +16 |
| 10 | -16 to +16 |
| 14 | -16 to +16 |
| 18 | -16 to +16 |
| 22 | -16 to +16 |
| 24 | -16 to +16 |

### 5.5.30 IMV + HFV Inadvertent PEEP Test

1. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV + HFV** |
| **PEEP/CPAP** | **Fully counterclockwise** |
| **Flow Rate** | **See below** |
| **Background Flow** | **See below** |
| **Ventilator Rate** | **See below** |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| **Inspiratory Time** | **See below** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| **Display Select** | **Expiration Time** |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| HFV Amplitude | Fully counterclockwise 3 - 4 turns (no hard stop) |

2. Verify that the PEEP/CPAP display is within limits. (See Section 5.6, item 34.)

| Flow Rate (Lpm) | Background Flow (Lpm) | Inspiratory Time (seconds) | Ventilator Rate (bpm) | PEEP/CPAP Limits ($cmH_2O$) |
|---|---|---|---|---|
| 40 | 30 | 0.50 | 60 | 0 to 5 |
| 30 | 30 | 0.33 | 90 | 0 to 5 |
| 20 | 20 | 0.15 | 120 | 0 to 5 |
| 10 | 10 | 0.10 | 150 | 0 to 5 |

### 5.5.31 Internal Battery Operation Test

The ventilator internal battery should be charged every 2 months to promote longer battery life (allow 2 hours to fully charge).

1. Charge the internal battery:
   a. Turn the ventilator OFF.
   b. Set the green circuit breaker switch ON.
   c. Connect the internal battery to an outside ac source and charge for 2 hours.

2. Set the following test conditions:

| | |
|---|---|
| **Mode** | **IMV** |
| PEEP/CPAP | Fully counterclockwise |
| **Flow Rate** | **20 Lpm** |
| **Background Flow** | **4 Lpm** |
| **Ventilator Rate** | **30 bpm** |
| Peak Inspiratory Pressure | 40 $cmH_2O$ |
| High Inspiratory Pressure | 45 $cmH_2O$ |
| **Inspiratory Time** | **1.0 second** |
| Low Inspiratory Pressure | 3 $cmH_2O$ |
| Display Select | Expiration Time |
| Oxygen Percent | 60 |
| Pressure Relief Valve | Fully clockwise |
| HFV Rate | 12 Hz |
| **HFV Amplitude** | **Fully clockwise 3 - 4 turns (no hard stop)** |

windows in diagno
window 6 - 3V Ref
E31 - Vent INOP
3V Ref Bad +/- 10% of 3V
3V Ref = 5V ÷ 256 = .01953
154 usually seen in window in diagnostic.
154 x .01953 = 3 Volts

**NOTE:**
Once the battery is fully charged, it can be tested in the IMV mode.

3. Turn ventilator power ON, unplug the ac power cord and verify:
   - Displayed values do not change more than ±1.
   - EXT POWER LOSS LED is turned ON.
   - Ventilator delivers positive pressure breaths.
   - No active alarms.
4. The ventilator should run for a minimum of 30 minutes before it produces a low battery LED indication. Replace battery if failed. (See Section 5.6, item 35.)

## 5.5.32 Hour Meter

Note that the hour meter increased in time (tenths of an hour) during the unit checkout. (See Section 5.6, item 36.)

## 5.6 Troubleshooting

Use this troubleshooting information in conjunction with the preventive maintenance / extended tests.

1. **Ground line resistance 0.1 Ω or less failure**
   a. Check for short circuits across or visible damage to power cord.
   b. Verify secure connection of ground wires at terminal on weldment.
   c. Try another ac outlet.
2. **Leakage current out of specification**
   a. Check for damage to power cord.
   b. Replace power supply.
3. **Unit power-up test fails**
   a. Replace power switch. (Check all connections.)
   b. If unit displays error codes refer to Section 9.
   c. If unit fails upon power-up, replace MP2 PCA.
   d. If unit completes a self test then fails, replace MP101 PCA.
   e. Replace EPROMs.
4. **A05 test fails (high peak inspiratory pressure)**
   a. Adjust pressure relief fully clockwise.
   b. Replace Pressure Transducer PCA.
   c. Replace Analog PCA.
5. **Low air pressure switch test fails**
   a. Verify air source are within specs.
   b. Verify wiring of pressure switch #1.
   c. Recalibrate/replace pressure switch #1.
6. **Low oxygen pressure switch test fails**
   a. Verify oxygen source are within specs.
   b. Verify wiring of pressure switch #2.
   c. Recalibrate/replace pressure switch #2.
7. **Check valve test fails**
   • Replace air/oxygen check valve.
8. **Proximal pressure test fails**
   a. Verify functionality of manometer. Replace if necessary.
   b. Check for static field on Front Panel. (Wipe overlay with moist towel.)
   c. Re-zero manometer.
   d. If analog gauge is off, recalibrate R76 on Analog PCA.
   e. Check Proximal line for leaks.